Complete Summary

GUIDELINE TITLE

Guidelines for management of Bowen's disease: 2006 update.

BIBLIOGRAPHIC SOURCE(S)

Cox NH, Eedy DJ, Morton CA, Therapy Guidelines and Audit Subcommittee, British Association of Dermatologists. Guidelines for management of Bowen's disease: 2006 update. Br J Dermatol 2007 Jan;156(1):11-21. [70 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cox NH, Eedy DJ, Morton CA. Guidelines for management of Bowen's disease. *Br J Dermatol* 1999; 141:633-41.

COMPLETE SUMMARY CONTENT

SCOPE

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IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Bowen's disease

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Dermatology Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the management of Bowen's disease

TARGET POPULATION

Patient's with Bowen's disease

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Observation (no treatment)
- 2. 5-fluorourcil
- 3. Topical imiquimod
- 4. Photodynamic therapy
- 5. Curettage with cautery/electrocautery
- 6. Cryotherapy
- 7. Excision
- 8. Radiotherapy
- 9. Laser treatment

MAJOR OUTCOMES CONSIDERED

- Ease of application/time required for procedure
- Wound healing
- Cosmetic result
- Costs of method

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I: Evidence obtained from at least one properly designed, randomized controlled trial

II-i: Evidence obtained from well-designed controlled trials without randomization

II-ii: Evidence obtained from well-designed cohort or case–control analytical studies, preferably from more than one centre or research group

II-iii: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence

III: Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees

IV: Evidence inadequate owing to problems of methodology (e.g., sample size, or length of comprehensiveness of follow up, or conflicts in evidence)

METHODS USED TO ANALYZE THE EVIDENCE

Review

Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

- A. There is good evidence to support the use of the procedure
- B. There is fair evidence to support the use of the procedure
- C. There is poor evidence to support the use of the procedure

- D. There is fair evidence to support the rejection of the use of the procedure
- E. There is good evidence to support the rejection of the use of the procedure

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength of recommendations (A-D) and quality of evidence (I-IV) and are defined at the end of the Major Recommendations field.

Summary of the Main Management Recommendations

- 1. Routine investigation for internal malignancy in patients with Bowen's disease (BD) is not justified **(E, I)**.
- 2. The risk of progression to invasive cancer is about 3%. This risk is greater in genital BD, and particularly in perianal BD. A high risk of recurrence, including late recurrence, is a particular feature of perianal BD and prolonged follow up is recommended for this variant (A, II-ii).
- 3. There is reasonable evidence to support use of 5-fluorouracil (5-FU) (B, II-i) but its use may be limited by irritancy and it was less effective than photodynamic therapy (PDT) in a randomized controlled trial (RCT). It is more practical than surgery for large lesions, especially at potentially poor healing sites, and has been used for 'control' rather than cure in some patients with multiple lesions.
- 4. Topical imiquimod is likely to be used for BD (B, I), especially for larger lesions or difficult/poor healing sites. However, it is costly, currently unlicensed for this indication, and the optimum regimen has yet to be determined.
- 5. Topical PDT has been shown to be equivalent or superior to cryotherapy and 5-FU, either in efficacy and/or in healing, in randomized controlled trials (A, I). It may be of particular benefit for lesions that are large, on the lower leg or at otherwise difficult sites, but it is costly. Photodynamic therapy for nonmelanoma skin cancer (NMSC) and premalignant skin lesions has now been approved as an interventional procedure by the National Institute for Health and Clinical Excellence in the United Kingdom, and methyl aminolaevulinate photodynamic therapy (MAL-PDT) has been approved by the European Medicines Authority for treatment of BD.

- 6. Curettage has good evidence of efficacy, and time to healing is faster than with cryotherapy (A, II-ii).
- 7. Cryotherapy has good evidence of efficacy (**B**, **II-i**), but discomfort and time to healing are inferior to photodynamic therapy (**A**, **I**) or curettage (**A**, **II-ii**).
- 8. Excision should be an effective treatment with low recurrence rates, but the evidence base is limited and for the most part does not allow comment on specific sites of lesions (A, II-iii). Lower leg excision may be limited by lack of skin mobility. For perianal BD treated surgically, wide excision is recommended rather than narrow excision or laser treatment (A, II-iii). Micrographic surgery is logical at sites such as digits or penis where it is important to limit removal of unaffected skin (B, III) and is useful for poorly defined or recurrent head and neck BD (B, II-iii).
- Radiotherapy has good evidence of efficacy but poor healing on the lower leg suggests that it should be avoided at this site (B, II-iii; for lower leg lesions D, II-III).
- 10. There is limited evidence on laser treatment, suggesting that it is a reasonable option for digital or genital lesions (B, II-iii) but probably not for other sites (mostly C or D, II-iii to IV); specifically, results for perianal BD are worse than those using wide surgical excision.

Table. Summary of the main treatment options for Bowen's disease. The suggested scoring of the treatments listed takes into account the evidence for benefit, ease of application or time required for the procedure, wound healing, cosmetic result and current availability/costs of the method or facilities required. Evidence for interventions based on single studies or purely anecdotal cases is not included.

Lesion Characteristics	Topical 5-FU	Topical Imiqumod ^a	Cryotherapy	Curettage	Excision	PDT	Radiothera
Small, single/few, good healing site ^c	4	3	2	1	3	3	5
Large, single, good healing site ^c	3	3	3	5	5	2	4
Multiple, good healing site ^c	3	4	2	3	5	3	4
Small, single/few, poor healing site ^c	2	3	3	2	2	1-2	5
Large, single, poor healing site ^c	3	2-3	5	4	5	1	6
Facial	4	7	2	2	4 ^d	3	4
Digital	3	7	3	5	2 ^d	3	3

Lesion Characteristics	Topical 5-FU	Topical Imiqumod ^a	Cryotherapy	Curettage	Excision	PDT	Radiothera
Perianal	6	6	6	6	1 ^e	7	2-3
Penile	3	3	3	5	4 ^d	3	2-3

^{1,} probably treatment of choice; 2, generally good choice; 3, generally fair choice; 4, reasonable but not usually required; 5, generally poor choice; 6, probably should not be used; 7, insufficient evidence available.

Definitions:

Strength of Recommendations

- A. There is good evidence to support the use of the procedure
- B. There is fair evidence to support the use of the procedure
- C. There is poor evidence to support the use of the procedure
- D. There is fair evidence to support the rejection of the use of the procedure
- E. There is good evidence to support the rejection of the use of the procedure

Quality of Evidence

- I: Evidence obtained from at least one properly designed, randomized controlled
- II-i: Evidence obtained from well-designed controlled trials without randomization
- **II-ii**: Evidence obtained from well-designed cohort or case–control analytical studies, preferably from more than one centre or research group
- **II-iii**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
- **III**: Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees
- **IV**: Evidence inadequate owing to problems of methodology (e.g., sample size, or length of comprehensiveness of follow up, or conflicts in evidence)

CLINICAL ALGORITHM(S)

None provided

^aDoes not have a product licence for Bowen's disease.

^bDepends on site.

^cRefers to the clinician's perceived potential for good or poor healing at the affected site.

^dConsider micrographic surgery for tissue sparing or if poorly defined/recurrent.

^eWide excision recommended.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of Bowen's disease

POTENTIAL HARMS

- 5-Fluorouracil can be very irritant.
- Ulceration can occur with cryotherapy.
- Lower leg excision wounds may be associated with considerable morbidity.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines have been prepared for dermatologists on behalf of the British Association of Dermatologists (BAD) and are based on the best data available at the time the report was prepared. Caution should be exercised when interpreting data where there is a limited evidence base; the results of future studies may require alteration of the conclusions or recommendations in this report. It may be necessary or even desirable to depart from the guidelines in the interests of specific patients and special circumstances. Just as adherence to guidelines may not constitute defence against a claim of negligence, so deviation from them should not necessarily be deemed negligent.
- All recommendations in this guideline are extrapolated from literature on Bowen's Disease (BD) and knowledge of other neoplastic skin lesions, and are presented on the understanding that neither the authors nor the British Association of Dermatologists (BAD) can formally recommend an unlicensed treatment.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Patient Resources For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2007 Jan)

GUIDELINE DEVELOPER(S)

British Association of Dermatologists - Medical Specialty Society

SOURCE(S) OF FUNDING

British Association of Dermatologists

GUIDELINE COMMITTEE

British Association of Dermatologists Therapy Guidelines and Audit Subcommittee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: N.H. Cox, Department of Dermatology, Cumberland Infirmary, Carlisle, UK; D.J. Eedy, Craigavon Area Hospital, Craigavon, UK; C.A. Morton, Stirling Royal Infirmary, Stirling, UK

British Association of Dermatologists Therapy Guidelines and Audit Committee Members: A.D. Ormerod (Chairman); D.J. Eedy; D. Mitchell; F. Humphreys; J. Peters; R. Bull; H. Bell; M. Kouimtzi; S. Jones

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Relevant product details are given in parentheses for the first citation of any pharmaceutical company below.

N.H.C. has received support for attendance at non-product-related educational meetings from Valeant Pharmaceuticals (5-fluorouracil cream); has acted as an advisor regarding development of pathways of care for basal cell carcinoma, sponsored by 3M Pharmaceuticals (imiquimod); and has a performed a sponsored clinical trial for Photocure of photodynamic therapy (PDT) using methyl aminolaevulinic acid for Bowen's disease. He has performed unsponsored research on cryotherapy and radiotherapy for Bowen's disease.

D.J.E. has received fees for speaking and chairing meetings for 3M Pharmaceuticals, travelling expenses from Leo Pharmaceuticals, and is an advisor to Novartis (U.K.).

C.A.M. has received sponsorship for speaking and chairing meetings from Galderma (Metvix®, a brand of methyl aminolaevulinic acid), and sponsorship from 3M and Leo Pharmaceuticals. He has performed sponsored as well as unsponsored research to evaluate the potential of topical photodynamic therapy using various photosensitizers in dermatological indications.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>British Association of Dermatologists Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

A list of possible Audit Points is provided in the <u>original guideline document</u>.

PATIENT RESOURCES

The following is available:

• Bowen's disease. Patient information leaflet. London (England): British Association of Dermatologists; 2007 Jun. 3 p.

Available from the <u>British Association of Dermatologists Web site</u>.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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